

RFP-NIAID-DMID-NIHAI2013178
Amendment #3

***“PHASE 1 CLINICAL TRIAL UNIT FOR THERAPEUTICS AGAINST
INFECTIOUS DISEASES”***

Amendment Issue Date: February 14, 2014

Proposal Due Date/Time: **March 20, 2014 at 3:00 P.M.**, local time
[UnChanged]

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Offerors must acknowledge receipt of this Amendment on each copy of the proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your proposal.

The date specified for receipt of proposals HAS NOT been extended.

THIS AMENDMENT ALSO PROVIDES CLARIFICATION TO VARIOUS QUESTIONS

- 1. Question:** Will the SDCC run automated data reports for the reporting of study status from the clinical database?

Answer: The SDCC will run reports for the data they house. Offerors should include in their proposal which reports to generate.

2. **Question:** We assume that the cost for the tasks performed by the ISM has to be included in the proposal? Is this correct?

Answer: No. Offerors should review and adhere to the full text of the NIH Policies, regarding “Data and Safety Monitoring in Clinical Trials”. This information can be found by accessing the web sites on the top page 83, of the Request for Proposals (RFP). Additional information can also be found by accessing the “Clinical Terms of Award” website found on Attachment 3, page 6 of 12, Section B. 3.a.

3. **Question:** We assume that the SDCC provides the actual EDC tool/database for data entry at the site and that we will not need to provide an EDC tool and data management service? Is this correct?

Answer: That assumption is correct.

Question: We incorporate in our proposal only the resolution to the queries and assume the SDCC will manage the query resolution tracking and processing. Is this correct?

Answer: That assumption is correct.

4. **Question:** We assume that the bar code on the label is to be used at the bioanalytical laboratory only – so not scan reading is required at the Phase I unit. Is this correct?

Answer: That assumption is correct.

Question: We assume that the DMID will provide a final data set in electronic format (CD) for archiving? Is this correct?

Answer: That assumption is correct.